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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,487	12/11/2007	Young-Tae Chang	CHANG184A	9141
1444 7590 12/22/2010 Browdy and Neimark, PLLC 1625 K Street, N.W. Suite 1100 Washington, DC 20006			EXAMINER LUNDGREN, JEFFREY S	
			ART UNIT 1639	PAPER NUMBER
			MAIL DATE 12/22/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,487

Applicant(s)

CHANG, YOUNG-TAE

Examiner

JEFFREY S. LUNDGREN

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 1-8 are pending in the instant application and are the subject of the Office Action below.

Claim Rejections - 35 USC § 112 – Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and all the dependent claims, are indefinite for reciting the limitation “the boronic acid” in the final two lines of claim 1, because there is improper antecedent basis. It is not clear if this limitation is the same as the boronic acid selector, or to a new boronic acid.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, Applicants do not have adequate support for the amended limitation “whereby the boronic acid shifts the equilibrium of the reaction to the desired isomer”. Although this may be a generic description of one specific reaction set forth in the specification at

paragraphs 0031-0032, the specification does have adequate support for this broad generic limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are anticipated by Petasis:

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Petasis et al., U.S. Patent No., 6,927,294, issued on August 9, 2005 – the rejection is maintained.

Applicants argue that the rejection is improper because the boronic acid of the prior art does not shift the equilibrium to the reaction of the desired isomer.

This argument is not persuasive as it is a reactant towards producing the final product, and therefore does shift the reaction to a desired isomer.

Reiterated Rejection:

The claimed invention is directed towards a method for producing a library of “dynamic” carbohydrates by subjecting a carbohydrate “scaffold” to intramolecular acyl migration using a boronic acid selector.

Petasis teaches a method for preparing functionalized nitrogen heterocyclic compounds, including benzodiazepines and azasugars, and synthetic methods for preparing such compounds. Nitrogen-containing heterocycles are prepared by reacting amino-carbonyl compounds that contain an amine moiety connected via a linker to a carbonyl moiety with an organoboron derivative (see Abstract). Specifically, Petasis teaches forming a library with the reaction chemistry of scheme 6 that is encompassed by claim 1:

“Thus, compounds 20 can be readily prepared via the incorporation of the amine moiety onto a **suitably protected carbohydrate derivative** to form 23, using known methods, as illustrated Scheme 6. For example, beginning with a sugar 25, selective protection followed by tosylation leads to 24, followed by amine incorporation to form 23 and deprotection under acidic conditions gives 20. Intermediate 23 can also be produced

via the reductive amination of carbohydrate-like precursor 25 or 26. Aldehyde 27 can be formed via the oxidation of protected alcohol 28. A more substituted derivative (ketone 26) can be prepared from 27 via variety of known methods, such as addition of Grignard reagents and oxidation.

These methods allow for the short synthesis of novel substituted azasugars and is directly suitable for the generation of combinatorial libraries of such compounds. This approach also allows the introduction of diverse functional groups by using **various boronic acids and starting sugars**. The products 22 can be subsequently transformed to produce new compounds. Subsequent transformations of products 22 can lead to a variety of **monocyclic or bicyclic derivatives**, including the types of compounds shown in Table 2. For example, these techniques can be used to generate azasugars 29 and 30, pipecolic acids 31, indolizidines 32a, 33a or 34a and quinolizidines 32b, 33b or 34b. Since the reactions proceed in a stereospecific manner, compounds of types 29-34 can be produced in enantiomerically pure form, beginning with particular sugar starting materials.”

Petasis, col. 15, lines 33-67.

As in claim 2, Petasis teaches a carbohydrate scaffold of monomers (see scheme 6); and as in claim 3, Petasis teaches “dimers and oligomers”, such as where Z is a polymeric chain (note: the claim reads on compounds that start as oligomer scaffolds, and do not require that the carbohydrate be the repeating unit).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are obvious over Bourne and Petasis:

Claims 1-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bourne et al., Journal of Chromatography A, Volume 11(2):253-257 (1963), in view of Petasis et al., U.S. Patent No., 6,927,294, issued on August 9, 2005.

Applicants argue that the rejection is improper because the boronic acid of the prior art does not shift the equilibrium to the reaction of the desired isomer, and does not occur via intramolecular acyl migration.

This argument is not persuasive as it is a reactant towards producing the final product, and therefore does shift the reaction to a desired isomer. Based on the art of record, the reaction does appear to result in an acyl migration.

Reiterated Rejection:

Bourne teaches that benzene-boronic acid [PhB(OH)₂] (I) reacts with several polyhydroxy compounds to give cyclic esters. A number of carbohydrates were chromatographed on Whatman No. 1 paper with solvent systems EtOAc-AcOH-H₂O (9:2:2) alone or contg. 0.55% I; spots were detected with K periodatocuprate and rosaniline. R_f values were markedly increased by adding I to the solvent. Acyclic polyhydroxy compounds, in general, showed much higher R_f values in the solvent containing the aldoses or ketoses from which they were derived, providing a rapid method for separating pairs of such, and R_f values are tabulated for 62 carbohydrates and related compounds.

Bourne does not explicitly teach the acyl migration of the boronic acid compound.

Petasis teaches a method for preparing functionalized nitrogen heterocyclic compounds, including benzodiazepines and azasugars, and synthetic methods for preparing such compounds. Nitrogen-containing heterocycles are prepared by reacting amino-carbonyl compounds that contain an amine moiety connected via a linker to a carbonyl moiety with an organoboron derivative (see Abstract). Specifically, Petasis teaches forming a library with the reaction chemistry of scheme 6 that is encompassed by claim 1:

“Thus, compounds 20 can be readily prepared via the incorporation of the amine moiety onto **a suitably protected carbohydrate derivative** to form 23, using known methods, as illustrated Scheme 6. For example, beginning with a sugar 25, selective protection followed by tosylation leads to 24, followed by amine incorporation to form 23 and deprotection under acidic conditions gives 20. Intermediate 23 can also be produced via the reductive amination of carbohydrate-like precursor 25 or 26. Aldehyde 27 can be formed via the oxidation of protected alcohol 28. A more substituted derivative (ketone 26) can be prepared from 27 via variety of known methods, such as addition of Grignard reagents and oxidation.

These methods allow for the short synthesis of novel substituted azasugars and is directly suitable for the generation of combinatorial libraries of such compounds. This approach also allows the introduction of diverse functional groups by using **various boronic acids and starting sugars**. The products 22 can be subsequently transformed to produce new compounds. Subsequent transformations of products 22 can lead to a variety of **monocyclic or bicyclic derivatives**, including the types of compounds shown in Table 2. For example, these techniques can be used to generate azasugars 29 and 30, pipercolic acids 31, indolizidines 32a, 33a or 34a and quinolizidines 32b, 33b or 34b. Since the reactions proceed in a stereospecific manner, compounds of types 29-34 can be produced in enantiomerically pure form, beginning with particular sugar starting materials.”

Petasis, col. 15, lines 33-67.

As in claim 2, Petasis teaches a carbohydrate scaffold of monomers (see scheme 6); and as in claim 3, Petasis teaches “dimers and oligomers”, such as where Z is a polymeric chain (note: the claim reads on compounds that start as oligomer scaffolds, and do not require that the carbohydrate be the repeating unit).

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of Bourne and Petasis are directed towards the production of a library of carbohydrate scaffold compounds using boronic acid derivatives. One of ordinary skill in the art would have recognized the refined chemical synthesis routes of Petasis in view of the approach of Bourne to make a library of compounds, such as oligomers of sugars including inositol, for chromatographic separations. Therefore, the invention as a whole was prima facie obvious at the time it was made.

Conclusions

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported in *ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is (571)272-5541. The Examiner can normally be reached from 7:00AM to 5:30 PM (Mon-Thu).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-09510951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey S. Lundgren/

Primary Examiner, Art Unit 1639